Complete Summary

GUIDELINE TITLE

Autologous chondrocyte implantation.

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Autologous chondrocyte implantation. Olympia (WA): Washington State Department of Labor and Industries; 2002 Jun. 3 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Work-related cartilaginous defects of the femoral condyle

GUIDELINE CATEGORY

Technology Assessment
Treatment

CLINICAL SPECIALTY

Internal Medicine
Orthopedic Surgery
Surgery

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals

Nurses
Physician Assistants
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for autologous chondrocyte implantation (ACI) in the injured worker

TARGET POPULATION

Injured workers who meet the criteria for autologous chondrocyte implantation (ACI)

INTERVENTIONS AND PRACTICES CONSIDERED

Autologous chondrocyte implantation (ACI)

MAJOR OUTCOMES CONSIDERED

- Knee function after autologous chondrocyte implantation
- Cost-effectiveness
- Cincinnati knee and pain scores
- Rates of complications and treatment failures
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Patient Registry Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search of autologous chondrocyte implantation clinical data included English articles in or after 1998, but excluded review articles.

Genzyme provided unpublished February 2002 outcomes data from a voluntary American patient registry.

In addition, abstracts from the American Academy of Orthopaedic Surgeons annual meeting were collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Studies were grouped according to study design and examined within the context of the American Academy of Neurology Classification of Evidence Guidelines.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Three studies were reviewed that examined autologous chondrocyte implantation's (ACI's) cost-effectiveness. The first study concluded that ACI resulted in a slightly lower return-to-work rate with an average net cost savings of $15,874 compared to patients not treated with ACI.

The second study concluded that ACI reduces the number of patients on disability as well as absenteeism. The procedure produces a cost savings of $88,146.

The third study concluded that ACI is a cost-effective treatment that provides improved quality of life for patients with full-thickness cartilage defects of the knee.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline developer considered policies from the following groups: American Academy of Orthopaedic Surgeons, various health insurers and the Centers for

Medicare and Medicaid Services, and the National Institute for Clinical Excellence of the National Health Service in the United Kingdom.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

What is Autologous Chondrocyte Implantation?

Autologous chondrocyte implantation (ACI) may treat patients with cartilaginous defects of the femoral condyle. The ACI process involves:

- obtaining healthy chondrocyte cells from a patient's knee
- culturing the cells through a process termed Carticel
- implanting the cultured chondrocytes back into the patient via a surgical procedure

When is ACI a covered procedure?

Carticel and ACI are covered procedures in patients who meet ALL of the following criteria.

A. An acute, work-related trauma to the knee caused the cartilaginous lesion. For example, the full-thickness cartilage loss is secondary to a shearing injury or a direct blow.

AND

B. Evidence shows a single, clinically significant, symptomatic lesion.
   i. The lesion affects a load-bearing surface of the medial femoral condyle or the lateral femoral condyle.

   and

   ii. The full-thickness lesion (Modified Outerbridge Grade II-IV) involves only cartilage.

   and

   iii. The lesion measures between 1 and 10 cm^2 in area.

AND

C. Evidence shows that the knee is stable and has:
   i. Intact, fully functional menisci and ligaments

   and

   ii. Normal alignment

and

iii. Normal joint space

AND

D. The patient attempted and failed BOTH of the following treatments for the lesion:
   i. Appropriate non-surgical treatment (e.g., minimum 2 months of physical therapy)

      and

   ii. Traditional surgical intervention (i.e., microfracture, drilling, abrasion, osteochondral graft). Debridement alone does not constitute a traditional surgical intervention for these purposes.

AND

E. The patient has the following characteristics:
   i. Less than 60 years old

      and

   ii. Body Mass Index <35

      and

   iii. Is capable and willing to follow the rehabilitation protocol

When is ACI not a covered procedure?

ACI is not a covered procedure in any of the following circumstances.

A. The lesion that requires treatment:
   i. Involves any portion of the patellofemoral articular cartilage

      or

   ii. Involves bone

      or

   iii. Is due to osteochondritis dissecans

OR

B. A "kissing lesion" of Modified Outerbridge Grade II, III, or IV exists on the opposing tibial surface.

OR

C. The patient has an arthritic condition that appears on standing x-rays as joint space narrowing, osteophytes, or changes in the underlying bone. The insurer will exclude a patient if the inflammatory (rheumatoid or other) or degenerative (osteoarthritis) arthritis is any of the following.

   a. Mild and diffuse

      or

   b. Moderate to severe and localized

      or

   c. Moderate to severe and diffuse

OR

B. The patient has an unhealthy cartilage border. The synovial membrane in the joint may be used as a substitute border for up to one-fourth of the total circumference.

OR

C. The patient has undergone a total meniscectomy of either compartment in the affected knee. The compartment in which the patient will receive ACI must contain at least one-third of the posterior meniscal rim.

OR

D. The patient has a history of anaphylaxis to Gentamicin or a sensitivity to materials of bovine origin.

OR

E. Chondrocalcinosis is diagnosed during the cell culturing process.

What documentation does the physician submit?

The Insurer may require physicians to submit the following documents to define the patient's knee condition:

A. Operative notes
B. Reports of standing x-rays
C. Arthroscopy results

For information on billing codes for ACI, refer to the original guideline document.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence was not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Autologous chondrocyte implantation (ACI) may benefit some patients with full-thickness chondral defects involving the surface of the femoral condyle.
- Published midterm and long-term case series data suggest that ACI improves patient outcomes and restores knee function. Published histological case studies also indicate that ACI may show increased durability due to the hyaline-like matrices of the repair tissue. Conference abstracts present some evidence that ACI is as effective as alternative treatments. However, researchers have not published in peer-reviewed journals any controlled studies documenting ACI's effectiveness.
- The literature shows that physicians have performed ACI outside of United States Food and Drug Administration indications and company recommendations. Due to the possible misuse of ACI, narrow patient and surgeon criteria for the procedure would help to ensure that the surgery occurs for appropriate indications.

POTENTIAL HARMS

Patient Registry Data

- Of the American patient registry's 6,286 patients, 5.8% reported adverse events or complications. The most frequent complications possibly related to autologous chondrocytes included adhesions or fibroarthrosis (1.6%), treatment failures (1.3%), and hypertrophic changes to the defect site (1.1%)
- Cumulative incidence rates of treatment failure were calculated as:
    - 0.7% at 12 months
    - 1.8% at 36 months
    - 3.3% at 72 months
- Of all patients, 4.8% reported reoperations following autologous chondrocytes implantation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Autologous chondrocyte implantation. Olympia (WA): Washington State Department of Labor and Industries; 2002 Jun. 3 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Jun

GUIDELINE DEVELOPER(S)

Washington State Department of Labor and Industries - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

Washington State Department of Labor and Industries

GUIDELINE COMMITTEE

Washington State Department of Labor and Industries

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Washington State Department of Labor and Industries Web site.

Print copies: Available from the L & I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Autologous chondrocyte implantation [ACI] 2002 update. Washington State Department of Labor and Industries, 2002 Jun 26. 22 p.

Electronic copies: Available in Portable Document Format (PDF) from the Washington State Department of Labor and Industries Web site.

Print copies: Available from the L & I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 5, 2004. The information was verified by the guideline developer on May 20, 2004.

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